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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/384,811	08/27/1999	PEGGY LEMAUX	18941000710U	8311
20350	7590	11/05/2003	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/384,811	LEMAUX ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on September 15, 2003 has been entered.

Claims 1-8 and 24-25 are cancelled.

Claims 9-23 are pending.

Claims 17-23 are withdrawn.

Claims 9-12 are currently amended.

Claims 9-16 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 9-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. (The Plant Journal, 1997, Vol. 11, No. 1, pages 157-165) in view of Wan et al. (Plant Physiol., 1994, Vol. 104, pages 37-48) and Bancroft et al. (Mol. Gen. Genet., 1992, Vol. 233, 449-461), further in view of Ritala et al., (Plant Molecular Biology, 1994, Vol. 24, pages 317-325), Funatsuki et al., (Theor. Appl. Genet., 1995, Vol. 91, pages 707-712), Koprck et al., (Plant Science, 1996, Vol. 119, pages 79-91), Brinch-Pedersen et al., (Plant Molecular Biology, 1996, Vol. 32, pages 611-620), and Jensen et al., (Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pages 3487-3491), for the reasons of record set forth in the office action mailed March 12, 2003.

Claims 15-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. (The Plant Journal, 1997, Vol. 11, No. 1, pages 157-165) in view of Wan et al. (Plant Physiol., 1994, Vol. 104, pages 37-48) and Bancroft et al. (Mol. Gen. Genet., 1992, Vol.

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233, 449-461), further in view of Ritala et al., (Plant Molecular Biology, 1994, Vol. 24, pages 317-325), Funatsuki et al., (Theor. Appl. Genet., 1995, Vol. 91, pages 707-712), Koprek et al., (Plant Science, 1996, Vol. 119, pages 79-91), Brinch-Pedersen et al., (Plant Molecular Biology, 1996, Vol. 32, pages 611-620), and Jensen et al., (Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pages 3487-3491), and further in view of Perera et al. (Plant Molecular Biology, 1993, Vol. 23, pages 793-799), for the reasons of record set forth in the office action mailed March 12, 2003.

The previously cited references of Ritala et al., Funatsuki et al., Koprek et al., Brinch-Pedersen et al., and Jensen et al. are added to the rejection of the claims under 35 U.S.C. 103(a) in response to the amendment of claim 9, which now requires the generation of a stably transformed barley plant. The teachings of Ritala et al., Funatsuki et al., Koprek et al., Brinch-Pedersen et al., and Jensen et al. with respect to the generation of stably transformed barley plants are set forth at page 6 of the office action mailed March 12, 2003.

Applicant's arguments filed September 15, 2003, have been fully considered but they are not persuasive.

In response to the Examiner's previous assertion that the claims do not require stable transformation of barley, Applicants point out that the claims as amended now require the generation of stable barley transformants. Applicants also traverse the Examiner's previous assertion that stable inheritance of functional heterologous transgenes in barley was well known in the art at the time of Applicant's invention, and that one skilled in the art would therefore reasonably expect to be successful in generating stable barley transformants comprising a functional Ac or Ds transgene. Applicants point out that stable transformants require stable integration into the genome, retention of the ability to transpose, and retention of the ability to

reinsert into the genome. Applicants argue that although the cited art may describe the stable inheritance of functional transgenes, such disclosure provides no basis for predicting the successful transposition and reinsertion of Ds elements. Applicants reiterate that, as set forth in the Declaration of Dr. Lemaux, at the time of Applicants invention it was known that the high level of methylation of the barley genome and heterologous sequences introduced therein frequently resulted in genetic instability and/or gene silencing, and that in order to retain their ability to excise and reinsert Ds elements must not be methylated or altered in sequence.

Applicants argue that given the high degree of methylation and known instability of sequences in the barley genome, one skilled in the art could not have predicted that Ds elements introduced into the barley genome would retain their structure and function over time. Applicants point out that the cited art provides no evidence of the stability of inverted repeats in the barley genome, and argue that the combined references provide only a motivation to try the Ac/Ds system in barley to generate stable transformants, for which there would be no reasonable expectation of success (reply pages 4-6).

With respect to the previously cited art providing a basis for predicting the successful transposition and reinsertion of Ds elements, the Examiner maintains that such a basis is provided. Ds elements are not unique in being subject to functional inactivation by methylation or sequence alteration as a consequence of rearrangement, as all transgenes are susceptible to such effects. In teaching the stable inheritance of functional transgenes in transgenic barley plants, the previously cited art provides a basis for predicting the successful transposition and reinsertion of Ds elements, as these transgenes, like Ds elements, would be subject to functional

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inactivation by methylation or sequence alteration as a consequence of rearrangement. The Examiner does not dispute the general assertion that at the time of Applicant's invention the barley genome was known to be highly methylated, or that heterologous sequences introduced therein frequently resulted in genetic instability and/or gene silencing. The Examiner maintains, however, that the teachings of the previously cited art showing the stable inheritance of numerous different functional transgenes indicates that it was also known at the time of Applicant's invention that the high degree of methylation of the barley genome did not preclude the stable inheritance of functional transgenes in transgenic barley. While Applicants correctly point out that the cited art provides no evidence of the stability of inverted repeats in the barley genome, Applicants provide no additional explanation for why such stability would not be expected on occasion, given that it was known that other types of transgenes could be stably inherited in barley. The Examiner additionally notes that genetic instability and gene silencing are known to affect transgenes to varying degrees in all plant systems, and that the rejected claims do not require anything more than the generation of a single stably transformed barley plant comprising a reintegrated Ds element.

With respect to the assertion that the combined references do not motivate one skilled in the art to use the Ac/Ds system in barley to generate stable transformants with a reasonable expectation of success, the Examiner notes that the rejection is not solely predicated on the teachings of the previously cited art showing the stable inheritance of numerous different functional transgenes. The rejection is also predicated on the teachings of Bancroft et al., showing that the Ac/Ds system can function in a heterologous plant system, and McElroy et al., showing that Ac and Ds can function in barley cells. The Examiner maintains that the knowledge

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that the Ac/Ds system can function in a heterologous plant system, and the knowledge that Ac and Ds can function in barley cells, combined with the knowledge that numerous different functional transgenes can be stably inherited in barley, would motivate one skilled in the art to use the Ac/Ds system in barley to generate stable transformants with a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

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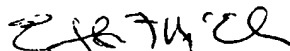
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
October 23, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600